

Notice of Allowability

Application No.

10/621,670

Applicant(s)

RAY ET AL.

Examiner

Art Unit

Evelyn Huang

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3-28-2005.
2. ☒ The allowed claim(s) is/are 8,9,11,12,16,17,19 and 20.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

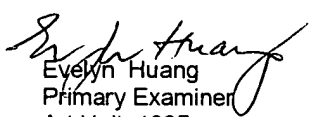
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Evelyn Huang
Primary Examiner
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Thallemer on 5-16-2005. During the interview, the examiner suggested amending claims 16-21 to be consistent with the description in the specification.

- a. Claim 16,
 - (i) replace 'mixing desloratadine, fumaric acid, and ethanol' with – mixing an ethanolic solution of desloratadine and fumaric acid --.
 - (i), before 'to form a solid', insert – and stirring for 30-45 minutes at this temperature--.
 - (ii), after 'filtering the solid', insert – at this temperature --.
- b. Claim 17,
 - (a), before 'ethanol', insert – anhydrous --.
 - (b), after 'ethanol', insert – anhydrous --.
 - (c), before 'to form a solid', insert – and stirring for 30-45 minutes at this temperature--.
 - (d), after 'filtering the solid', insert – at this temperature --.
- c. Cancel claim 18.
- d. Claim 19,
 - (i) replace 'mixing desloratadine, fumaric acid, and ethanol' with – mixing an ethanolic solution of desloratadine and fumaric acid --.
 - (i), before 'to form a solid', insert – and stirring for 30-45 minutes after mixing--.
 - (ii), after 'filtering the solid', insert – at this temperature --.

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- e. Claim 20,
- (a), before 'ethanol', insert – anhydrous --.
 - (b), after 'ethanol', insert – anhydrous --.
 - (c), before 'to form a solid', insert – and stirring for 30-45 minutes after mixing--.
 - (d), after 'filtering the solid', insert – at this temperature --.
- f. Cancel claim 21.
- g. In the specification, page 1, after the title, line 1, insert – This application claims the benefit of 60/401,153, filed on 8-5-2002 --.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

Claims 8, 9, 11, 12, 16, 17, 19, 20 are allowed.

The cancellation of claims 14, 15 has rendered moot the rejection under 35 U.S.C. 103(a) as being unpatentable over Villani (4659716, PTO-1449) in view of Hansen (5658899) and/or Strupczewski (4954503) and/or Congy (5290951).

Villani (4659716, PTO-1449) discloses descarbonylethoxyloratadine and the pharmaceutically acceptable salts (including the fumarate and the hydrates thereof, column 26, claim 3; column 1). Lacking is the teaching or suggestion to prepare the instant polymorph form 1 or 2 of descarbonylethoxyloratadine hemifumarate having the characteristic X-ray diffraction pattern.

WO 99/01450 (PTO-1449) or Schumacher (6506767, the US equivalent of WO 99/01450) discloses polymorphs of descarbonylethoxyloratadine. The instant is a polymorph form of descarbonylethoxy-loratadine hemifumarate having X-ray diffraction patterns different from Schumacher's polymorphs. Absent is the teaching or suggestion to prepare the instant polymorph form 1 or 2 of descarbonylethoxy-loratadine hemifumarate having the characteristic X-ray diffraction pattern.

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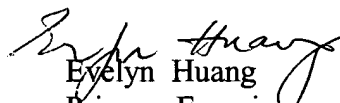
Furthermore, the instant polymorphs 1 and 2 has high water solubility, and the stability study indicates that the instant polymorphs 1 and 2 are more stable than free base desloratadine under stressed condition. Both polymorphs do not change the polymorphic form even after crushing into a solid powder form (pages 3-4 of the specification).

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625